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CONTRACT NO: 92MM2504

TITLE: ORBITAL FLOOR RECONSTRUCTION WITH BONE REPAIR

PRINCIPAL INVESTIGATOR: MICHAEL H. MAYER

ORGANIZATION ADDRESS: Walter Reed Army Medical Center
U.S. Army Institute of Dental Research
Washington, DC 20307-5001

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In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Animal Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

For the protection of human subjects, the investigator(s) have adhered to policies of applicable Federal Law 45 CFR 46.

In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

 30 SEP 92
Principal Investigator's Signature Date

QUARTERLY REPORT

1. MIPR No. 92MM2504 2. Report Date 12 Mar 92
3. Reporting period from 1 Dec 91 to 28 Feb 92
4. P.I. LTC Michael H. Mayer, MC 5. Telephone No. (202)576-1560
6. Agency and Address Asst Chief, Plastic Surgery Service, Walter Reed
Army Medical Center, Washington, D. C. 20307-5001
7. Project Title: Orbital Floor Reconstruction with Bone Repair
Materials

8. Current staff, with percent effort of each on project:

LTC Michael H. Mayer, MC 50%

COL Jeffrey Hollinger, DC 50%

9. Approximate PI expenditures to date:

Personnel _____ Supplies _____

Travel _____ Other _____

Equipment _____ Contracts \$3,600 (Histological slide preparation)

10. Narrative Summary of Activities during Quarter (continue on separate sheet if necessary): The initial 18 NHPS were turned in to preclude per diem charges while awaiting the availability of a recombinant, highly purified bone inductive protein (BIP). Initially a partially purified BIP was planned for the implant, but would be of limited merit now.

11. Use the reverse side and additional pages as necessary, to describe scientific progress for the quarter in terms of the tasks or objectives listed in the statement of work for this effort. Explain deviations where this isn't possible. Include data where possible.

12. Use the reverse side to present a brief statement of plans or milestones for the next quarter.

11. Awaiting availability of the recombinant, highly purified BIP and reissue of the NHPS. This protein is to be used in alveolar clefts in dogs in March 1992.

12. Initial grafting of the orbit defects is tentatively planned for May/June 1992. The total duration of the project is three months. The NHPS would be sacrificed approximately September 1992.

Problems for Consideration:

1. The interagency agreement raised the MHP per diem from the initially requested \$2.60/day to the present \$3.85/day/NHP. This per diem increase will require payments of \$2,080 per month for three months for a total of \$6,240. The initial per diem allocation was \$4,212.

2. This protocol along with the protocols from MIPR #92MM2505 and MIPR #92MM2506 require the acquisition of a fulltime research associate/surgical assistant whose duties would encompass surgical responsibilities, animal caretaking responsibilities, data collection and data analysis, clerical responsibilities including literature searches, as well as overall coordination of these research projects. The projected yearly salary would be \$40,000, and immediate hiring would require \$20,000 for this fiscal year. PCS moves, retirements, and changes in supervisory personnel have created this requirement.

3. A portable computer and software for data collection, data analysis, and routine clerical work/word processing related to the project and projects from MIPR #92MM2505 and MIPR #92MM2506 are requested at an approximate cost of \$4,800.

QUARTERLY REPORT

1. MIPR No. 92MM2504 2. Report Date 12 Jun 92
3. Reporting period from 1 May 92 to 31 May 92
4. P.I. LTC Michael H. Mayer, MC 5. Telephone No. (202)576-1560
Asst Chief, Plastic Surgery Service, Walter Reed
6. Agency and Address Army Medical Center, Washington, D. C. 20307-5001
7. Project Title: Orbital Floor Reconstruction with Bone Repair
Materials

8. Current staff, with percent effort of each on project:

LTC Michael H. Mayer, MC 50%

COL Jeffrey Hollinger, DC 50%

9. Approximate PI expenditures to date:

Personnel _____ Supplies _____

Travel _____ Other _____

Equipment _____ Contract _____

10. Narrative Summary of Activities during Quarter (continue on separate sheet if necessary): No non-human primates have been reacquired to pursue this project.

11. Use the reverse side and additional pages as necessary, to describe scientific progress for the quarter in terms of the tasks or objectives listed in the statement of work for this effort. Explain deviations where this isn't possible. Include data where possible.

12. Use the reverse side to present a brief statement of plans or milestones for the next quarter.

11. The highly Purified BIP will not be available in sufficient quantities to complete the project this fiscal year.

12. Request re-issue of these MIPR funds to 92 MM 2506 and 92 MM 2506 to offset the increased per diem rates and contribute to the requirement for a research associate/surgical assistant and computer which were delineated in the last report. NO communication on these requirements has been received.

QUARTERLY REPORT

1. MIPR No. 92MM2504 2. Report Date 15 Sep 92
3. Reporting period from 1 Jun 92 to 31 Aug 92
4. P.I. LTC Michael H. Mayer, MC 5. Telephone No. (202) 576-1560
6. Agency and Address Assistant Chief, Plastic Surgery Service, Walter Reed Army Medical Center, Washington, DC 20307-5001
7. Project Title: Orbital Floor Reconstruction with Bone Repair Materials
-
8. Current staff, with percent effort of each on project:
- LTC Michael H. Mayer, MC (50%)
- COL Jeffrey Hollinger, DC (50%)
-
9. Approximate PI expenditures to date:
- | | | | |
|-----------|-----------------------------|-----------|--|
| Personnel | <u> </u> | Supplies | <u> </u> |
| Travel | <u> </u> | Other | <u> </u> |
| Equipment | <u> </u> | Contracts | <u>Harrington Arthritis Research Center</u>
<u>\$3,600 (histological slide preparation)</u> |
10. Narrative Summary of Activities during Quarter (continue on separate sheet if necessary):
- (see reverse side)
11. Use the reverse side and additional pages as necessary, to describe scientific progress for the quarter in terms of the tasks or objectives listed in the statement of work for this effort. Explain deviations where this isn't possible. Include data where possible.
12. Use the reverse side to present a brief statement of plans or milestones for the next quarter.

10. No non-human primates have been reacquired to pursue this project.

11. Due to the lack of highly purified BIP and lack of facilities/non-human primates, the project could not be completed this fiscal year.

12. Request re-issue of these MIPR funds for fiscal year 1993. In addition to the \$15,012.00 from the initial MIPR, the following funds will be required to complete the project:

Animal Costs: 18 monkeys @ \$2400/virus-free monkey = \$43,000

Per diem: Initially calculated @ \$2.40/day/non-human primate, the per diem rate ranges from \$6.00-\$9.00/day/non-human primate at the present.

90 days x \$9.00 x 18 monkeys = \$14,580.00

\$14,580.00 - \$4,212.00 (initial per diem) = \$10,368.00

Research Associate/Surgical Assistant: Full-time research associate whose duties would encompass surgical responsibilities, animal caretaking responsibilities, data collection and data analysis, clerical responsibilities including literature searches, as well as overall coordination of research projects.

Yearly salary - \$40,000. This cost could be divided between MIPR #92MM2505 and MIPR #92MM2506 (\$40,000 x 1/3 = \$13,333).

Equipment: A portable computer and software for data collection, data analysis, and routine clerical work/word processing related to the project and projects from MIPR #92MM2505 and MIPR #92MM2506 are requested at an approximate cost of \$4,800 (\$4,800 x 1/3 = \$1,600).

TOTAL ADDITIONAL FUNDS: \$68,301.00